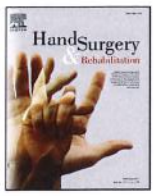
Hand Surgery and Rehabilitation xxx (2018) xxx–xxx

Available online at
ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com



Original article

Revision surgery in carpal tunnel syndrome: a retrospective study comparing the Canaletto® device alone versus a combination of Canaletto® and Dynavisc® gel

Chirurgie de reprise du syndrome du canal carpien : étude rétrospective comparant l'implant Canaletto® seul versus l'implant Canaletto® plus gel Dynavisc®

A. Carmona, J.J. Hidalgo Diaz, S. Facca, Y. Igeta, C. Pizza, P. Liverneaux *

Department of hand surgery, SOS main, CCOM, university hospital of Strasbourg, FMTS, University of Strasbourg, Icube CNRS 7357, 10, avenue Baumann, 67400 Illkirch, France

ARTICLE INFO

Article history:
Received 6 September 2018
Received in revised form 25 September 2018
Accepted 8 October 2018
Available online xxx

Keywords:
Carpal tunnel
Canaletto
Median nerve
Neurolysis
Recurrence
Anti-adhesion gel

Mots-clés:
Canal carpien
Canaletto
Nerf médian
Neurolyse
Récidive
Gel antiadhésion

ABSTRACT

The aim of our study was to demonstrate the benefits of combining the Canaletto® implant with carboxymethylcellulose/polyethylene oxide gel in the surgical treatment of carpal tunnel syndrome (CTS) recurrences.

Our case series included 39 patients (40 hands, one bilateral case) who underwent revision surgery for recurrent CTS (28 cases) or resistant CTS (12 cases). The mean age of the patients was 56 years. The Canaletto® only was implanted in the first 21 cases (group I). In the following 19 cases (group II), Dynavisc® gel was added to the protocol and applied around the median nerve when the Canaletto® was implanted.

At 12 months' follow-up (group I) and 11 months' follow-up (group II), the pre-versus post-operative difference between the average values of the DN4 neuropathic Pain Score was 0.55/10 in group I and 2.25/10 in group II; the Pain Score was 2.23/10 (in group I) and 2.52/10 (in group II); the Quick DASH Score was 18.98/100 (group I) and 19.06/100 (in group II); the hand grip strength was 19.55% (group I) and 28.53% (group II); the sensory nerve conduction velocity was 8.67 m/s (group I) and 10.27 m/s (group II); the distal motor latency was 1.05 m/s (group I) and 1.75 m/s (group II). Nine patients recovered from hypoesthesia in both groups, 5 patients regained satisfactory trophism of the thenar muscles in group I and 3 patients in group II. No improvement whatsoever was noted in 2 patients in group II, despite the electromyogram being normal. One patient from group II suffered an infection that required revision surgery to remove the Canaletto®; this led to a moderate improvement.

Our results show that when resistant or recurrent CTS is diagnosed, the combined treatment of an anti-adhesion gel such as Dynavics® around the median nerve with the Canaletto® implant after performing secondary neurolysis leads to satisfactory post-operative outcomes. Compared to other techniques described in the current literature, our technique is less invasive, quicker and associated with minimal morbidity of the surgical site.

RÉSUMÉ

Le but de ce travail était de tester l'intérêt d'associer un implant Canaletto® à un gel composé de carboxyméthylcellulose et de polyéthylène oxyde dans le traitement chirurgical des récidives de syndrome du canal carpien (SCC).

* Corresponding author: Department of hand surgery, university hospital of Strasbourg, 10, avenue Baumann, 67403 Illkirch cedex, France
E-mail address: Philippe.liverneaux@chru-strasbourg.fr (P. Liverneaux).

https://doi.org/10.1016/j.hansur.2018.10.244
2468-1229/

Please cite this article in press as: Carmona A, et al. Revision surgery in carpal tunnel syndrome: a retrospective study comparing the Canaletto® device alone versus a combination of Canaletto® and Dynavisc® gel. Hand Surg Rehab (2018), https://doi.org/10.1016/j.hansur.2018.10.244

La série comprenait 39 patients soit 40 mains opérées pour la deuxième fois d'un SCC récidivant (28 cas) ou récalcitrant (12 cas) par neurolyse. L'âge moyen était de 56 ans. Un implant Canaletto® a été mis en place chez les 21 premiers cas (groupe I). Un gel Dynavisc® a été appliqué autour du nerf médian, puis un implant Canaletto® a été mis en place chez les 19 derniers cas (groupe II).

Au recul moyen de 12 mois (groupe I) et 11 mois (groupe II), la variation pré/postopératoire du DN4 était en moyenne de 0,55/10 dans le groupe I et de 2,25/10 dans le groupe II, de la douleur 2,227/10 (groupe I) et 2,52/10 (groupe II), du score Quick DASH 18,98/100 (groupe I) et 19,06/100 (groupe II), de la force de poigne de la main 19,55% (groupe I) et 28,53% (groupe II), de la vitesse de conduction nerveuse sensitive de 8,67 m/s (groupe I) et 10,27 m/s (groupe II), de la latence motrice distale de 1,05 m/s (groupe I) et 1,75 m/s (groupe II), 9 patients ont récupéré une hypoesthésie dans les 2 groupes, 5 patients ont récupéré une bonne trophicité des muscles thénariens externes dans le groupe I et 3 patients dans le groupe II. Deux patients du groupe II n'étaient pas améliorés alors que les signes électromyographiques étaient normalisés. Un patient du groupe II a présenté une infection qui a nécessité l'ablation de l'implant Canaletto® avec une légère amélioration finale.

Nos résultats semblent montrer qu'en présence d'un syndrome récidivant ou récalcitrant du canal carpien, l'association d'un gel anti-adhérant Dynavics® autour du nerf médian à la mise en place d'un implant Canaletto® après neurolyse donne de bons résultats. Par rapport aux autres techniques la littérature, notre technique est moins invasive, plus rapide, sans morbidité au site donneur.

1. Introduction

Failure of primary surgery in carpal tunnel syndrome (CTS) is not rare. Revision surgery rates range from 0 to 19% [1,2]. Some authors have reported satisfactory post-operative outcomes when secondary release of the median nerve is performed in combination with a Canaletto® implant [3]. This implant is sutured on both margins of the transected flexor retinaculum; it widens the cross-section of the carpal tunnel and recreates a gliding space for the volar surface of the median nerve. Other authors have demonstrated the advantages of using an anti-adhesion gel (carboxymethylcellulose and polyethylene oxide) to reduce epidural post-operative fibrosis and improve the clinical efficacy of discectomy and laminectomy in spine surgery [4].

The aim of our study was to determine whether it would be beneficial to combine the Canaletto® implant with a carboxymethylcellulose/polyethylene oxide gel in the surgical treatment of CTS recurrences.

The main hypothesis was that the difference between the neuropathic Pain Score assessed preoperatively and postoperatively through the DN4 is greater in the group treated with Canaletto® and Dynavisc® than in the group treated with the Canaletto® device alone. The secondary hypothesis was that the difference between the preoperative and post-operative values of quantitative clinical outcomes (pain, grasp, Quick DASH), qualitative clinical outcomes (paresthesia, atrophy) and electromyographic variables (sensory conduction velocity and distal motor latency) is greater in the group treated with Canaletto® and Dynavisc® than in the group treated with the Canaletto® device alone.

2. Material and methods

The local ethics committee authorized this retrospective study. All the medical records of patients who had undergone revision surgery for recurrent or resistant CTS between 2014 and 2016 were reviewed. All patients who suffered complications (Type I complex regional pain syndrome, infection, iatrogenic nerve lesions) despite the resolution of paresthesia, all patients who had persistent paresthesia associated with cervical nerve compression syndrome, all patients younger than 18 years old or pregnant and any patients lost to follow-up were excluded from the study. Patients who had undergone revision surgery for recurrent or persistent CTS with a Canaletto® device (Eurymed™, Nîmes, France) were included in the study. During the primary surgery, all patients were operated through a 15-mm volar incision along a line crossing the third interosseous space.

Our case series included 39 patients and 40 hands (1 bilateral case) who had undergone revision surgery due to recurrent or resistant CTS (Tables 1 and 2). The 28 recurrence cases were diagnosed after a symptom-free interval of 873 weeks on average and the 12 resistant cases had persistence of paresthesia after surgery. The patients' age ranged from 29 years to 82 years with an average of 56 years. Five patients presented with a polyneuropathy. The indication for revision surgery was made based on electroneuromyogram (ENMG) results.

All the patients in our case series were operated under regional anesthesia in a day surgery setting and with use of an arm tourniquet. The primary scar was excised and the carpal tunnel was approached through a 25-mm volar incision. The new flexor retinaculum appeared macroscopically thickened on exploration in all cases except three, especially in its distal segment. After longitudinal section of the new retinaculum over its entire length and accessing the carpal tunnel, the position of the median nerve in the tunnel was found to be normal in 11 cases, deviated radially in 25 cases and superficial in 1 case. The macroscopic appearance of the median nerve was normal in 5 cases and was congested, flattened or opaque in the remaining cases. Flexor tendon synovitis was found in the majority of the cases (30/40). Extra-fascicular release of the median nerve was carried out next. Flexor tendon synovectomy was not performed.

In the first 21 cases (group I), a Canaletto® device (Eurymed™, Nîmes, France) was implanted. The silicone surface on the deep portion of this device was placed in direct contact with the median nerve. Both margins of the device were then sutured to both margins of the neoretinaculum with two 3/0 nylon sutures. In the last 19 cases (group II), a carboxymethylcellulose/polyethylene oxide gel (Dynavisc®, Fziomed™, San Luis Obispo, CA, USA) was applied around the median nerve along its entire course in the carpal tunnel (Fig. 1). Next, a Canaletto® device was implanted as described above (same technique as group I). The skin was closed with three 4/0 nylon suture points. No post-operative splinting was prescribed, and all patients were encouraged to move their wrist and fingers immediately. Strenuous movements were allowed 6 weeks after the surgery.

The outcomes assessment consisted of measuring sensory, motor and functional variables preoperatively and postoperatively

Please cite this article in press as: Carmona A, et al. Revision surgery in carpal tunnel syndrome: a retrospective study comparing the Canaletto® device alone versus a combination of Canaletto® and Dynavisc® gel. Hand Surg Rehab (2018), https://doi.org/10.1016/j.hansur.2018.10.244

Table 1
Case series of 21 revision surgeries of carpal tunnel syndrome treated with Canaletto®.

	Patient						Characteristics				Intraoperative findings	
n	Age (years)	Sex (F/)	Dominant side (R/L)	Affected side (R/L)	Occupation (Mn/S/Ret)	Symptom free (weeks)	OD (Y/N)	PNP (Y/N)	Retinaculum appearance (N/T)	Nerve position (N/R/U/S)	Nerve appearance (N/E/F/L)	Flexor tenosynovtis (Y/N)
1	32	F	R	R	Mn	0	Y	N	T	Rad	F	N
2	82	M	R	L	S	72	N	Y	T	N	L	Y
3	57	F	R	R	S	240	Y	N	T	Rad	E	N
4	44	F	R	R	Mn	40	Y	N	N	N	O/F	Y
5	45	F	R	L	Mn	336	N	N	N	N	F	N
6	73	F	R	L	S	0	N	N	T	Rad	E	Y
7	72	M	R	L	S	0	N	N	T	Rad	E	Y
8	74	M	R	R	S	144	N	N	T	Rad	E/F	Y
9	58	F	R	R	Mn	96	N	N	T	Sup	E	Y
10	29	M	R	R	Mn	96	N	N	T	N	F	Y
11	58	F	R	R	Mn	24	N	N	T	Rad	N	Y
12	70	F	R	R	S	192	N	N	T	N	E	Y
13	34	F	R	R	Mn	96	N	N	T	Rad	N	Y
14	68	F	R	L	Ret	44	N	N	T	N	E	Y
15	51	F	R	R	Mn	112	Y	N	T	Rad	E	Y
16	55	M	R	R	S	28	N	N	T	N	N	N
17	46	F	R	R	S	96	N	N	T	N	E	Y
17a	46	F	R	L	S	96	N	N	T	N	E	Y
18	38	F	R	R	S	20	N	N	T	N	E	Y
19	55	F	L	L	Mn	24	N	N	T	Rad	N	Y
20	55	F	R	R	Mn	1248	Y	N	T	N	E	Y

M: male; F: female; R: right; L: left; Mn: manual; S: sedentary; Ret: retired; OD: occupational disease; PNP: polyneuropathy on EMG. Retinaculum appearance: N: normal; T: thickened. Nerve position: N: normal; Rad: radial; U: ulnar; Sup: superficial. Nerve appearance: N: normal; E: edema; A: flattened; L: nerve lesion.

Table 2
Case series of 19 revision surgeries of carpal tunnel syndrome treated with Canaletto® + Dynavisc® gel.

	Patient								Characteristics		Intra-operative findings	
n	Age (years)	Sex (F/)	Dominant side (R/L)	Affected side (R/L)	Occupation (Mn/S/Ret)	Symptom free (weeks)	OD (Y/N)	PNP (Y/N)	Retinaculum appearance (N/T)	Nerve position (N/R/U/S)	Nerve appearance (N/E/F/L)	Flexor tenosynovitis (Y/N)
1	57	F	R	L	Mn	0	Y	N	T	Rad	E	Y
2	66	F	R	L	S	118	N	N	T	Rad	E	Y
3	57	F	R	L	Mn	6240	Y	Y	T	Rad	E	Y
4	56	F	R	L	Mn	0	Y	N	T	Rad	E	Y
5	51	F	R	R	S	4	N	N	T	U	E	N
6	46	M	R	R	Mn	0	N	N	T	M	E/F	N
7	53	F	R	R	Mn	106	?	N	T	Rad	E	Y
8	52	M	R	R	S	13728	N	Y	T	Rad	E	Y
9	69	M	R	R	S	4	N	N	T	Rad	E/L	Y
10	47	M	R	R	Mn	68	N	N	T	Rad	E	Y
11	68	M	R	R	S	288	N	N	T	Rad	E	Y
12	66	F	R	L	S	192	N	N	T	Rad	E/F	Y
13	59	F	R	R	S	60	N	N	T	Rad	NL	N
14	63	M	R	L	S	0	N	N	T	Rad	E	N
15	73	F	R	R	S	736	N	N	T	Rad	E	Y
16	49	F	R	R	Mn	0	N	Y	T	M	E	N
17	53	F	R	R	Mn	0	N	Y	N	Rad	E	N
18	77	M	R	R	S	0	N	N	T	Rad	F	Y
19	42	F	?	R	Mn	?	N	N	T	Rad	F	Y

M: male; F: female; R: right; L: left. Mn: manual; S: sedentary; Re: retired; OD: occupational disease; PNP: polyneuropathy on EMG. Retinaculum appearance: N: normal; T: thickened. Nerve position: N: normal; Rad: radial; U: ulnar; Sup: superficial. Nerve appearance: N: normal; E: edema; F: flattened; L; nerve lesion.

and then comparing the magnitude of these differences between groups. The DN4 Score is a questionnaire that determines whether or not the pain is neuropathic based on 10 variables. Four or more positive answers to the questionnaire are enough for the diagnosis of neuropathic pain [5]. The pain intensity was assessed through a visual analog scale ranging from a Score of 0 (no pain) to 10 (maximum intensity of pain). The Quick DASH score relevant to upper limb function was based on a questionnaire containing 11 variables: the total Score ranges from 0 (no functional impairment) to 100 (nonfunctional upper limb). The grip strength was measured in Kg using a Jamar® dynamometer set on position 2 (Arex™, Palaiseau, France). Neurological impairment was assessed and diagnosed based on the presence of hypoesthesia in the median nerve area and thenar muscle atrophy. ENMG was used to measure the velocity of sensory nerve conduction in m/s and the distal motor latency in m/s. Complications were documented in detail.

The objective of the statistical analysis was to establish whether a significant difference existed between the two groups between the preoperative and post-operative (documented at the very last follow-up appointment) values of each of the six matched quantitative variables (DN4, pain, Quick DASH Score, grip strength, sensory nerve conduction velocity, distal motor latency) and for each of the matched qualitative variables (hypoesthesia and atrophy).

Given the limited sample size in our study, the classical "frequentist" statistical model based on the *p* value would not have been suitable for our data analysis. Thus our analysis was carried

Please cite this article in press as: Carmona A, et al. Revision surgery in carpal tunnel syndrome: a retrospective study comparing the Canaletto® device alone versus a combination of Canaletto® and Dynavisc® gel. Hand Surg Rehab (2018), https://doi.org/10.1016/j.hansur.2018.10.244

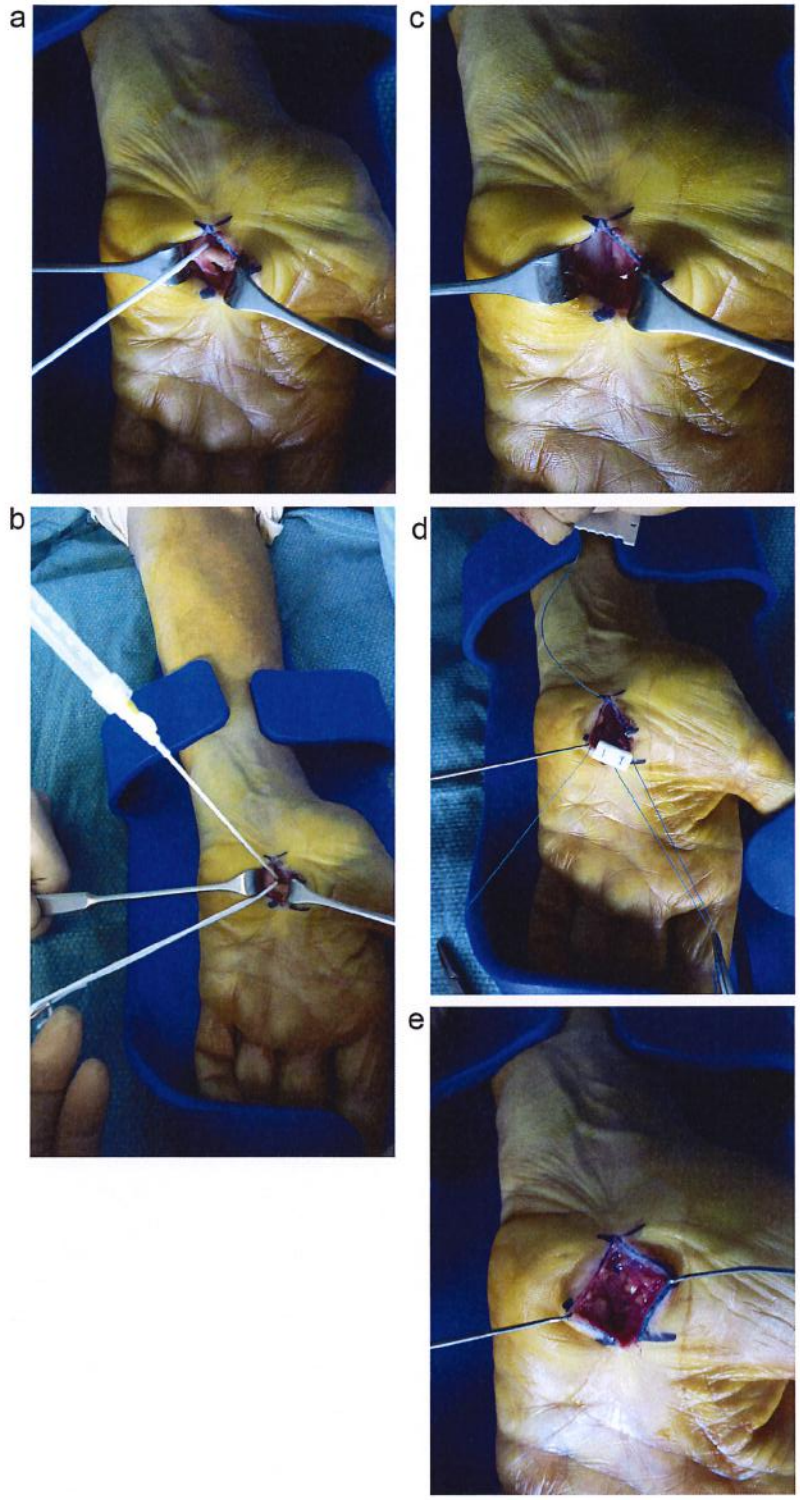


Fig. 1. Median nerve release, nerve isolated with a vascular loop (a). Dynavisc® gel injected on the entire surface (b). Median nerve after Dynavisc® gel injection on the entire length and surface of the released median nerve (c). Implantation of the Canaletto®. The deep aspect of Canaletto® is in direct contact with the median nerve. The margins of the Canaletto® are sutured to the margins of the flexor neoretinaculum with a 3/0 nylon suture (d). Intraoperative view after Canaletto® device implantation but before skin closure (e).

out using a Bayesian model, which calculates the likelihood of finding a difference. The likelihood of finding a difference was calculated as a value between 0 and 1 which provided more accurate information than the binary information of a p value ($P < 0.05$ or $P > 0.05$). A value of likelihood of a difference of credible intervals between the two groups higher than 90% was a strong difference, higher than 95% was a very strong difference, higher than 97.5% was a significant difference. All data were processed using version 3.1.0 of the "R" software and the JAGS software.

Please cite this article in press as: Carmona A, et al. Revision surgery in carpal tunnel syndrome: a retrospective study comparing the Canaletto® device alone versus a combination of Canaletto® and Dynavisc® gel. Hand Surg Rehab (2018), https://doi.org/10.1016/j.hansur.2018.10.244

3. Results

All results are reported in Tables 3 and 4. The average follow-up was 12 months in group I and 11 months in group II.

The difference between the pre-operative and post-operative value of the DN4 Score was on average 0.55/10 in group I and 2.25/10 in group II. Given the estimated difference of 76% and the average improvement difference of −1.863 [−3.59; −0.299], the likelihood that the pre-operative/post-operative difference in the DN4 Score in group II could be higher than the difference in group I was greater than 99%, which represents a significant difference.

The difference between the pre-operative and post-operative value of the Pain Score was on average 2.23/10 in group I and 2.52/10 in group II. Given the estimated difference was 12% and the average improvement difference was −0.663 [−2.478; −0.994], the likelihood that the pre-operative/post-operative difference in the pain Score in group II could be higher than the difference in group I was greater than 77%, which represents a non-significant difference.

The difference between the pre-operative and post-operative value of the Quick DASH Score was on average 18.98/100 in group I and 19.06/100 in group II. Given the estimated difference was 0.80% and the average improvement difference was −14.503 [−26.809; −0.869], the likelihood that the pre-operative/post-operative difference in the Quick DASH Score in group II could be higher than the difference in group I was greater than 98%, which represents a significant difference.

The difference between the preoperative and post-operative value of the grip strength was on average 19.55% in group I and 28.53% in group II. Given the estimated difference was 31% and the average improvement difference was −7.168 [−6.5; 20.9], the likelihood that the pre-operative/post-operative difference in the grip strength value in group II could be higher than the difference in group I was greater than 85%, which represents a significant difference.

The difference between the preoperative and post-operative value of sensory7 nerve conduction velocity was on average 8.67 m/s in group I and 10.27 m/s in group II. Given the estimated difference was 16% and the average improvement difference was 3.334 [−5.579; 12.133], the likelihood that the preoperative/post-operative difference in the sensory nerve conduction velocity in group II could be higher than the difference in group I was greater than 77%, which represents a non-significant difference.

The difference between the pre-operative and post-operative value of the distal motor latency was on average 1.05 m/s in group I and 1.75 m/s in group II. Given the estimated difference was 40% and the average improvement difference was 0.043 [−1.692; 1.745], the likelihood that the pre-operative/post-operative difference in distal motor latency in group II could be higher than the difference in group I was greater than 48%, which represents a non-significant difference.

Nine patients recovered from their hypoesthesia in group I and 9 patients in group II. Given the difference estimated was −1.2% [−33.69; 30.8], the likelihood that the recovery rate from hypoesthesia in group II could be higher than group I was 53.4%, which represented a non-significant difference.

Five patients regained good trophism of the thenar muscles in group I and 3 patients in group II. Being the estimated difference 2.9% [−9.0; 67.1], the likelihood that the recovery rate from thenar atrophy in group II was higher than group I was 6.8%, which represented a non-significant difference.

For 2 patients from group II (13 and 19), revision surgery was not beneficial. In both cases, unexplained pain persisted despite a normal ENMG. One patient from group II (6) suffered a surgical site infection from *Staphylococcus aureus* on the 6th week after surgery.

Table 3
Post-operative outcomes in a case series of 21 carpal tunnel syndrome revision surgeries treated with Canaletto®.

Patient	Delay	Follow-up	Pre-operative									Post-operative							
(*n*)	(months)	(months)	DN4 (0/10)	Pain (0/10)	Quick DASH (0-100)	Grip strength (% contralateral)	Hypoesthesia (Y/N)	Thenar atrophy (Y/N)	NCV (m/s)	Distal latency (m/s)	DN4 (0/10)	Pain (0/10)	Quick DASH (0–100)	Grip strength (% contralateral)	Hypoesthesia (Y/N)	Thenar atrophy (Y/N)	NCV (m/s)	Distal latency (m/s)
1	8	9	?	6	68.18	33.3	Y	N	0	5.4	?	5	45.45	41.7	Y	N	25.9	4.04
2	18	14	5	6	43.18	100	Y	N	45	4.2	4	4	15.91	92.8	Y	N	39	3.9
3	60	12	3	7	75.00	41.6	Y	N	35	3.3	7	9	86.36	29.3	N	N	36	3.6
4	10	15	6	8	52.27	20	Y	Y	36.6	4.3	5	9	36.36	109.1	Y	N	50	4.2
5	84	16	6	9	77.27	70	Y	N	41	3.4	6	7	68.18	80	Y	N	41	3.4
6	26	8	?	9	81.82	?	Y	N	0	10.7	?	5	52.27	105.9	Y	N	0	1.6
7	0	11	?	1	9.9	107	Y	Y	0	7.5	?	0	4.55	100	N	Y	0	9.74
8	36	11	6	9	56.82	66.6	Y	Y	0	6.15	2	1	9.09	66.6	N	N	32.1	5.45
9	24	11	2	6	47.73	50	N	N	37.4	3.5	0	0	0	100	N	N	42.9	2.9
10	24	11	4	1	50.00	47.1	Y	N	0	5	4	4	54.55	110	N	N	50	?
11	6	8	5	6	45.45	60	Y	N	41	2.8	5	4	45.45	76.2	Y	Y	?	?
12	48	18	2	6	34.09	47.8	Y	Y	0	0	2	0	27.27	66.6	Y	N	0	0
13	24	14	3	5	52.27	85.2	N	N	36.1	4.3	6	8	54.55	75.7	N	N	41.4	4.3
14	11	18	2	5	38.64	33.3	N	Y	28.3	8.1	0	0	0	100	N	Y	38	4.4
15	28	16	5	8	56.82	55.5	Y	Y	41.7	?	5	5	50	68.4	N	N	52.1	3.5
16	7	10	6	6.5	65.91	96.7	Y	Y	28	9.2	0	0	0	100	N	N	44	4.6
17	24	10	3	7	61.36	65.2	Y	N	48	3.5	1	1	13.64	127.3	N	N	44	2.8
17a	24	7	2	5	59.09	78.6	Y	N	45	3.8	2	2	13.64	75	N	N	50	3.2
18	5	7	3	5	61.36	28.6	Y	Y	14.2	13.8	5	5	52.27	50	N	Y	24.3	9.1
19	6	19	5	6	59.09	63.3	N	Y	42	0	4	4	63.64	69.4	N	Y	?	?
20	312	8	6	6	59.09	100	N	N	34.4	?	6	7	63.64	78.9	N	N	55	?

Delay: time elapsed between primary and revision surgery; DN4: neuropathy score; NCV: nerve conduction velocity; Y: yes; N: no.

Please cite this article in press as: Carmona A, et al. Revision surgery in carpal tunnel syndrome: a retrospective study comparing the Canaletto® device alone versus a combination of Canaletto® and Dynavisc® gel. Hand Surg Rehab (2018), https://doi.org/10.1016/j.hansur.2018.10.244

Table 4
Post-operative outcomes in a case series of 19 carpal tunnel syndrome revision surgeries treated with Canaletto® + Dynavisc® gel.

Patient	Delay	Follow-up	Pre-operative								Post-operative							
(n)	(months)	(months)	DN4 (0/10)	Pain (0/10)	Quick DASH (0-100)	Grip strength (% contralateral)	Hypoesthesia (Y/N)	Thenaratrophy (Y/N)	NCV (m/s)	Distal latency (m/s)	DN4 (0/10)	Pain (0/10)	Quick DASH (0–100)	Grip strength (% contralateral)	Hypoesthesia (Y/N)	Thenar atrophy (Y/N)	NCV (m/s)	Distal latency (m/s)
1	6	12	4	5	34.09	83.3	Y	N	26.9	9	2	1	11.3	100	N	N	46.9	4.8
2	114	10	4	5	59.09	69.6	Y	N	58.5	4.7	0	3	72.7	63	N	N	41.4	3.5
3	187	19	2	0	45.45	100	N	Y	0	8.75	2	0	34.0	82	Y	Y	28.9	9.01
4	10	23	4	7	79.55	30	Y	Y	22.7	5.7	0	5	43.1	68	N	Y	45.6	3.93
5	54	20	3	7	54.55	100	Y	N	33	4	3	6	59.0	104	Y	N	41	3.5
6	9	12	5	7	70.45	69.7	Y	Y	46	7.16	9	2	38.6	75	Y	Y	55.1	4.78
7	69	6	5	4	50	90	N	N	33.3	5.4	1	3	50	107	N	N	37.5	5.3
8	275	7	6	5	63.64	77	Y	Y	0	6.7	0	0	0	119	N	N	45.5	4
9	4	16	6	5	9.09	75	Y	Y	25.9	8.52	4	2	2.27	87	Y	N	23.8	2.81
10	31	16	4	2	50	44	Y	N	41.4	4.34	1	0	25	?	N	Y	?	?
11	98	8	4	5	20.45	110	Y	Y	?	?	0	1	13.6	122	N	Y	0	0
12	49	6	8	3	50	?	Y	Y	27.1	5.9	3	3	47.7	100	N	N	?	?
13	24	7.5	3	5	43.18	75	Y	Y	30.2	4.3	3	6	9.09	95	N	N	53.3	3.9
14	7	6	5	3	29.55	33	Y	N	34	6.3	0	0	4.55	200	Y	N	41	4.8
15	194	6	4	6	65.91	20	Y	Y	0	5.9	2	2	40.9	83	Y	Y	33	6
16	8	11	4	6	59.09	50	Y	N	47.9	3.95	4	3	70.4	75	Y	N	50	3.6
17	6	8	5	8	81.82	50	Y	N	21.4	4.9	0	0	13.6	85	N	N	44.1	4.5
18	108	10	4	4	52.27	85	Y	Y	30.8	7.51	5	0	29.5	55	Y	Y	32.9	6.62
19	23	9	4	5	59.09	40	Y	Y	43.3	10	?	7	50	?	Y	Y	48	6

Delay: time elapsed between primary and revision surgery; DN4: neuropathy score; NCV: nerve conduction velocity; Y: yes; N: no.

The patient was re-operated for Canaletto® removal and thorough lavage of the infection site. The infection resolved, and the CTS had a mild post-operative improvement from a clinical and electromyographic point of view.

4. Discussion

Failure of surgical treatment for CTS is due to two main causes: resistant syndromes (clinical signs and symptoms persist after primary surgery) and recurrent syndromes (signs and symptoms reappear after a 3-month symptom-free interval after the primary surgery) [6]. The most frequent cause of resistant syndrome is incomplete transection of the flexor retinaculum; less frequently the cause is an iatrogenic nerve lesion [7]. The most frequent cause for recurrent syndrome is perineural fibrosis [8].

Regardless of the reason why the primary nerve release failed, it is widely accepted that secondary nerve release should be combined with a procedure to reduce post-operative perineural fibrosis. Multiple techniques have been described such as the use of biomaterials [9] and a "wrapping" flap aimed at restoring a gliding plane for the nerve [10]. Regardless of the technique, the post-operative outcomes are often poor or unpredictable after multiple surgeries, as 43 to 90% of patients undergoing secondary surgery have persistent symptoms and among those, 20% cases have treatment failure [11,12]. The best results described in literature were associated with the use of the Canaletto® device [13].

Our study combined the Canaletto® device with absorbable Dynavisc® gel.

The Canaletto® device was placed through a relatively small incision, which was sufficiently long to allow accurate release of the median nerve and sufficiently short to avoid extensive dissection. Whenever the median nerve was found on exploration to be radially deviated in the carpal tunnel, secondary nerve release brought it to a less radial position. The Canaletto® implant has two major advantages. First, it prevents median nerve elongation by recreating a gliding surface (made of silicone) that protects its deeper aspect. Secondly, it prevents anterior nerve subluxation by recreating a wider retinaculum [3]. The two main disadvantages of the Canaletto® device are the risk of migration in the carpal tunnel when fixation to the neoretinaculum margins is carried out with absorbable sutures and the risk of impingement between the knots and the adjacent soft tissues when the fixation is performed with non-absorbable sutures. The latter complication was never observed in our case series. Secondly the anti-adhesion surface of the device is only present on its palmar aspect. For this reason, we believe combining it with Dynavisc® gel could be beneficial.

The Dynavisc® gel is a compound of two polymers: polyethylene oxide and carboxymethylcellulose. Polyethylene oxide is a high molecular weight polymer that prevents tissue adhesions thanks to its biochemical characteristics. It blocks fibrosis formation by inhibiting fibroblast recruitment and activation. Carboxymethylcellulose is a polymer that blocks adhesions by acting as a physical barrier [14]. The main advantage of this gel is its absorbability in 1 month by hydrolysis. Clinical studies in spine surgery [15] and gynecology [16] have confirmed these properties. Another advantage of this gel is that its application around the median nerve recreates a circumferential gliding space, which cannot be recreated with the Canaletto® alone. The price difference between Canaletto® and Dynavisc® is minimal; each one costs about 200 euros.

Among the weaknesses of our study is that the limited sample size affected the data interpretation. From a descriptive point of view, the two groups were not completely comparable. Four

Please cite this article in press as: Carmona A, et al. Revision surgery in carpal tunnel syndrome: a retrospective study comparing the Canaletto® device alone versus a combination of Canaletto® and Dynavisc® gel. Hand Surg Rehab (2018), https://doi.org/10.1016/j.hansur.2018.10.244

percent of the patients in group I and 21% of group II presented with a polyneuropathy. The diabetes comorbidity, a frequent cause of polyneuropathy, is associated with poor post-operative outcomes in secondary carpal tunnel surgery according to current literature [17,18]. None of our diabetic patients had poor outcomes. Three patients had persistent CTS in group I, and 7 in group II. Persistent CTS with no underlying iatrogenic cause or associated cervical compression syndrome is assumed to lead to worse post-operative outcomes compared to recurrent CTS [19]. Nevertheless, this was not observed in our 10 cases of resistant CTS.

Five patients in group I (patient 3, 4, 10, 13 and 20) did not improve after revision surgery. These patients did not have a past medical history of specific risk factors except for three patients for whom the CTS was an occupational disease (patients 3, 4, 20). The diagnosis of occupational disease is a negative prognostic factor itself for surgery [20].

The main hypothesis of our study was proven since the difference between the pre-operative and post-operative neuropathic pain assessed with the DN4 Score in the group of patients who underwent revision surgery with the combination of Canaletto® and Dynavics® was higher than the difference in patients treated with Canaletto® alone.

The secondary hypothesis relevant to the difference between the preoperative and post-operative Quick DASH Score was proven, since the difference in the Canaletto® and Dynavisc® gel group was higher compared to the group treated with Canaletto® alone. The remaining secondary hypothesis relevant to the other quantitative clinical variables (pain, strength), qualitative variables (paresthesia, amyotrophy) and ENMG variables (sensory nerve conduction velocity and distal motor latency) were not proven. In general, our findings suggest that when a resistant or recurrent CTS is diagnosed, secondary nerve release with combined application of Dynavics® gel around the median nerve and a Canaletto® implant lead to satisfactory clinical and functional results. Compared to other techniques described in the literature, our technique had the advantage of using a small incision which avoids the local morbidity associated with harvesting a wrapping flap for the median nerve. The advantages of using the Dynavisc® gel alone are still to be demonstrated.

Disclosure of interest

Philippe Liverneaux has conflicts of interest with Newclip Technics, Argomedical, Zimmer Biomet, Biomodex.
The other authors declare that they have no competing interest.

Acknowledgments

The company Fziomed™, San Luis Obispo, California USA who kindly provided 19 samples of Dynavisc®.

References

[1] Botte MJ, Schroeder HP, Abrams RA, Gellman H. Recurrent carpal tunnel syndrome. Hand Clin 1996;12:731–43.
[2] Chang B, Dellon AL. Surgical management of recurrent carpal tunnel syndrome. J Hand Surg Br 1993;18:467–70.
[3] Duché R, Trabelsi A, Dusserre F, Micallef JP. Retinaculum flexors: clinical and experimental anatomic bases in favor of reconstruction in carpal tunnel surgery. Chir Main 2003;22:65–72.
[4] Fransen P. Safety of carboxymethylcellulose/polyethylene oxide for the prevention of adhesions in lumbar disc herniation-consecutive case series review. Ann Surg Innov Res 2008;2:2.
[5] Bouhassira D, Attal N, Alchaar H, Boureau F, Brochet B, et al. Comparison of pain syndromes associated with nervous or somatic lesions and development of a new neuropathic pain diagnostic questionnaire (DN4). Pain 2005;114:29–36.
[6] Tung TH, Mackinnon SE. Secondary carpal tunnel surgery. Plast Reconstr Surg 2001;107:1830–43.
[7] Stütz N, Gohritz A, van Schoonhoven J, Lanz U. Revision surgery after carpal tunnel release-analysis of the pathology in 200 cases during a 2-year period. J Hand Surg Br 2006;31:68–71.
[8] Raimbeau G. Recurrent carpal tunnel syndrome. Chir Main 2008;27:134–45.
[9] Bilasy A, Facca S, Gouzou S, Liverneaux P. Canaletto implant in revision surgery for carpal tunnel syndrome: 21-case series. J Hand Surg Eur 2012;37:682–9.
[10] Strickland JW, Idler RS, Lourie GM, Plancher KD. The hypothenar fat pad flap for management of recalcitrant carpal tunnel syndrome. J Hand Surg Am 1996;21:840–8.
[11] Cobb TK, Amadio PC, Leatherwood DF, Schleck CD, Ilstrup DM. Outcome of reoperation for carpal tunnel syndrome. J Hand Surg Am 1996;21:347–56.
[12] Craft RO, Duncan SF, Smith AA. Management of recurrent carpal tunnel syndrome with microneurolysis and the hypothenar fat pad flap. Hand 2007;2:85–9.
[13] Duché R, Trabelsi A. The Canaletto®™ implant for reconstructing transverse carpal ligament in carpal tunnel surgery. Surgical technique and cohort prospective study about 400 Canaletto cases versus 400 cases with open carpal tunnel surgery. Chir Main 2010;29:352–9.
[14] Liu LS, Berg RA. Adhesion barriers of carboxymethylcellulose and polyethylene oxide composite gels. J Biomed Mater Res 2002;63:326–32.
[15] Rhyne AL, Blumenthal SL, Frank EH, Hsu KY, Kim KD, et al. Oxiplex reduces leg pain, back pain, and associated symptoms after lumbar discectomy. Spine 2012;37:631–41.
[16] Young P, Johns A, Templeman C, Witz C, Webster B, et al. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP gel: a pilot study. Fertil Steril 2005;84:1450–6.
[17] Al-Quattan MM, Manktelow RT, Bowen CVA. Outcome of carpal tunnel release in diabetic patients. J Hand Surg Br 1994;19:626–9.
[18] Karthik K, Nanda R, Stothard J. Recurrent carpal tunnel syndrome - analysis of the impact of patient personality in altering functional outcome following a vascularized hypothenar fat pad flap surgery. J Hand Microsurg 2012;4:1–6.
[19] Zieske L, Ebersole GC, Davidge K, Fox I, Mackinnon SE. Revision carpal tunnel surgery: a 10-year review of intra-operative findings and outcomes. J Hand Surg Am 2013;38:1530–9.
[20] Djerbi I, César M, Lenoir H, Coulet B, Lazerges C, Chammas M. Revision surgery for recurrent and persistent carpal tunnel syndrome: Clinical results and factors affecting outcomes. Chir Main 2015;34:312–7.

Please cite this article in press as: Carmona A, et al. Revision surgery in carpal tunnel syndrome: a retrospective study comparing the Canaletto® device alone versus a combination of Canaletto® and Dynavisc® gel. Hand Surg Rehab (2018), https://doi.org/10.1016/j.hansur.2018.10.244